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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,577	09/16/2003	Robert G. Dennis	UOM 0294 PUS	4495
22045 7590 05/31/2007 BROOKS KUSHMAN P.C. 1000 TOWN CENTER TWENTY-SECOND FLOOR SOUTHFIELD, MI 48075				
			EXAMINER GOUGH, TIFFANY MAUREEN	
			ART UNIT 1657	PAPER NUMBER
			MAIL DATE 05/31/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/663,577	<b>Applicant(s)</b> DENNIS ET AL.	
	<b>Examiner</b> Tiffany M. Gough	<b>Art Unit</b> 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,3-8,10-21 and 23-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-8,10-21 and 23-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

Applicant's response filed 2/26/2007 has been received and entered into the case.

Claims 1,3-8,10-21,23-40 are pending and have been considered on the merits. Claims 2,9,22 have been cancelled by applicant. All arguments and amendments have been considered.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1,17,32 (and all dependent claims) are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification, as originally filed, in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the amendment "...wherein only some of the cells are in contact with the anchors ..." and "...the substrate configured to ..." introduces new matter, which is not described in the specification. Applicant's amendment changes the scope of the invention from allowing at least some of the cells to attach, to ONLY allowing some of the cells to be in contact with the anchors, thus it appears as if only cells may be in contact with the anchors and nothing else. Further, "...the substrate configured to ..." changes the scope of the invention requiring configuration not described by applicant.

Therefore, the amendments change the scope of the claims and applicants invention for which no support is provided. This is a new matter rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 (and all its dependent claims) are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 has been amended to read "...the substrate configured to permit the monolayer to detach..." This statement is indefinite for the following reason: it does not seem that the monolayer necessarily DOES detach to self-organize into a three dimensional construct. The monolayer is "permitted" to detach but does not state that it absolutely does, nor does applicant claim how the substrate is "configured to" permit such detachment. It appears as if this configuration bears some functionality in detachment which has not been clarified by applicants amendment.

It appears as if applicant attempted to clarify the claim by amendment, however, the language "permit" is not absolute, thus applicants argument that the new amendment now recites a limitation of the substrate not the monolayer does not clear up if the monolayer does absolutely detach to form a 3-D construct.

Further, claim 1 has also been amended to read "...only some of the cells are in contact with the anchors..." The amendment creates confusion in that it is not clear if

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some of the cells are in contact with the anchors or if the cells are the only thing in contact with the anchors.

**The following 112 2<sup>nd</sup> rejection is maintained.**

The function of the “anchors” in claims 1,17, and 32 (and the therefore dependent claims 3-8,10-16,,18-21,23-31,33-40) is unclear. It appears that the anchors may actually be serving as a scaffold-like structure, enabling the cells to grow around the anchors allowing cell layers to form and enabling ingrowth of tissue. One skilled in the art may be led to consider the claimed “anchors” as a “scaffold” in regards to the vagueness of the word scaffold used in applicants invention. Furthermore, the spatial relationship of the anchors appears to be essential for the growth of cells in the invention and should be clearly defined. Therefore, claims 1,3-8,10-21,23-40 are rejected under 35 U.S.C 112, second paragraph.

Applicants arguments and amendments to the claims are not persuasive and do not clarify the relationship of the anchors in conjunction with “an exogenous scaffold material.” It still appears as if the anchors are serving as an exogenous scaffold material allowing cells to attach and grow on and in the anchors (see specification p.8, lines 13-18). Applicant argues that the new amendment “...wherein only some of the cells are in contact with the anchors...” separates the claimed exogenous scaffold from those known in the art, given that a “scaffold” is known to be a three dimensional growth surface into which a totality of cells are introduced. Applicant further argues that the anchors do not extend into the contractile region of the tissue. Scaffolds are known in

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the art to be useful in stimulating and promoting cell growth and do NOT require that the TOTALITY of cells be introduced within to function as a scaffold. Thus, applicants "anchors" which allow for ingrowth of cells (see spec. p.8, lines 13-25) does function as a scaffold material. The argument that the anchors do not extend into the contractile region of the tissue is not a limitation of the claim, thus the argument is not commensurate in scope. Thus, applicants arguments of the differences between the claimed anchors and scaffolds is not persuasive.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1,3-7,10-21,23-27,29,32-36 and 40 are/stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-

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3,5-9,12,13,15-19,21-23,26,28-31 of U.S. Patent No. 6,207,451 B1. For the reasons previously stated, the rejection is maintained.

Although the conflicting claims are not identical, they are not patentably distinct from each other because 6,207,451 B1 teaches that the mammalian muscle construct comprising myogenic precursor cells may include cardiac muscle cells, thus, the constructs and methods appear to be drawn to the same subject matter.

**In response to this rejection Applicants state they will address this rejection if claims of the current application become allowable.**

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tiffany M. Gough whose telephone number is 571-272-0697. The examiner can normally be reached on M-F 8-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tiffany Gough

/Ruth A. Davis/  
Primary Examiner  
AU 1651